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EXAMINER

STRZELECKA, TERESA E

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/404,520

Applicant(s)

CAO ET AL.

Examiner

Teresa E Strzelecka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: Notice to Comply, Raw Sequence Listing Error Report.

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DETAILED ACTION

1. This office action is in response to an amendment filed December 29, 2003. Claims 57 and 58 were previously pending. Applicants cancelled claim 57, amended claim 58 and added new claims 59-72. Claims 58-72 are pending and will be examined.

2. Applicants' claim cancellation and arguments overcame the following rejections: rejection of claim 57 under 35 U.S.C. 101 (utility); rejection of claims 57 and 58 under 35 U.S.C. 112, first paragraph (written description); rejection of claim 57 under 35 U.S.C. 103 (a) over Rodriguez-Tome et al. All other rejections are maintained for reasons given in the 'Response to Arguments' section.

Sequence Rules Compliance

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

APPLICANT IS GIVEN the time of response to this office action WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.F.R. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Response to Arguments

4. Applicant's arguments filed December 29, 2003 have been fully considered but they are not persuasive.

A) Regarding the rejection of claim 58 under 35 U.S.C. 101 (utility), Applicants argue that:

1) the methods find numerous uses, such as transcription profiling, identifying counterpart genes in other species and identifying ORFs,

2) golf clubs differ from each other but each has generic utility, therefore generic utility of nucleic acids does not compromise the specific utility,

3) using nucleic acid sequences recorded on a computer readable medium will identify unique set of related sequences,

4) sequences presented by Applicants have functions, e.g., SEQ ID NO: 16218 is a chitinase.

In general, the utility of the invention is considered on the basis of specific, substantial or well-established utility.

Regarding specific utility, Applicants did not show any for any of the claimed sequences. Despite the fact that these sequences have general (or generic, as stated by Applicants) utility, such as being used in transcription profiling, identifying counterpart genes or identifying ORFs, any other nucleic acid sequence ever published has such utility, therefore Applicants sequences do not possess specific utilities.

With respect to substantial utility, Applicants did not present any, either. Substantial utility cannot be given to an invention if further research is required in order to determine whether and how any of the Applicants' nucleic acids have utility. A need for further research clearly documents a lack of currently available utility.

Further, regarding Applicants arguments that some of the sequences have functions, these functions are putative, i.e., determined on the basis of a sequence comparison with a database of

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sequences. Even assuming that the functions were real, how does comparing a sequence of a chitinase presented by Applicants with a database of sequences differ from comparing a sequence of a chitinase from any other organism with a database of sequences? Such use does not constitute a specific or substantial utility, either. As to the arguments that the search results are unique, and going back to the chitinase sequence, the result of sequence search using Applicants' chitinase and any other chitinase will produce the same results (provided the searches are performed against the same databases), therefore there is nothing unique about this process, therefore it does not confer either specific or substantial utility on Applicants' sequences.

Finally, the sequences claimed in claim 58 and newly added claims 59-72 do not have a well-established utility, since the utility of these sequences is not well known or immediately apparent.

Regarding Applicants' argument citing the golf club analogy, it is an oversimplification of the basis of lack of utility rejections in this case. It is acknowledged that a number of inventions may accomplish some result that has utility and that setting forth another one is not negated by the presence of others that already accomplish a particular result. The basis of the lack of utility rejection is that there is no result that is in "currently available form", but rather only potential results that may or may not be available, and then only at best available via further research. It is acknowledged that any golf club has utility in a well-established sport, that being playing golf. No well established utility has been determined or set forth for any of the instant inventions.

Applicants argue that the Patent Office must accept assertions of utility as factual unless challenging it is set forth. The above discussion is deemed to sufficiently challenge the asserted utilities as non-specific and non-substantial for the reasons noted above. Applicants are reminded that the assessment of utility does not rely solely on credibility as a number of other bases have

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been summarized above. If an invention fails based on a lack of specific and substantial utility, credibility assessment is not needed since a lack of utility has already been established.

Therefore, the rejection is maintained, with the addition of new claims 59-72, as necessitated by Applicants' amendment.

B) Regarding the rejection of claim 58 under 35 U.S.C. 112, first paragraph (enablement), Applicants state that the same arguments are the same as for the lack of utility rejection. Since the above arguments have been responded to above as being non-persuasive, they are considered as non-persuasive with respect to the enablement rejection.

The rejection is maintained, with the addition of new claims 59-72, as necessitated by Applicants' amendment.

C) Regarding the art rejection, Applicants argue that claim 58 is a process of identifying a nucleotide sequence by comparing the sequence to at least 100 sequences stored on a computer readable medium. Applicants argue that claim 58 defines a process, which is statutory because it is a "practical application", and cite MPEP 2106 B.2.(b) in support. Applicants further argue that even if the sequences constitute a non-functional descriptive material, this does not render the methods unpatentable.

However, the distinction between the statutory and non-statutory process performed by a computer lies not in the fact that the process is some sort of a practical application, but in the fact of whether the process produces a tangible result, i.e., a physical transformation outside of the computer. In the same MPEP paragraph cited by Applicants, 2106 B.2.(b), there is a statement:

" If a physical transformation occurs outside the computer, a disclosure that permits a skilled artisan to practice the claimed invention, i.e., to put it to a practical use, is sufficient. On the other hand, it is necessary for the claimed invention taken as a whole to produce a practical application if there is only a transformation of signals or data inside a computer or if a process merely manipulates concepts or converts one set of numbers into another.

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A claimed process is clearly statutory if it results in a physical transformation outside the computer, i.e., falls into one or both of the following specific categories ("safe harbors").

Safe Harbors

- Independent Physical Acts (Post-Computer Process Activity)

A process is statutory if it requires physical acts to be performed outside the computer independent of and following the steps to be performed by a programmed computer, where those acts involve the manipulation of tangible physical objects and result in the object having a different physical attribute or structure. *Diamond v. Diehr*, 450 U.S. at 187, 209 USPQ at 8. Thus, if a process claim includes one or more post-computer process steps that result in a physical transformation outside the computer (beyond merely conveying the direct result of the computer operation), the claim is clearly statutory."

In the same section there is a clear example of the difference between a statutory and non-statutory computer processes, the example involving noise analysis and noise filtering (see below, emphasis added). Whereas noise analysis is confined to pure computational process without producing any tangible results, noise filtering results in a physical transformation which occurs outside of the computer.

" Computer-Related Processes Limited to a Practical Application in the Technological Arts

There is always some form of physical transformation within a computer because a computer acts on signals and transforms them during its operation and changes the state of its components during the execution of a process. Even though such a physical transformation occurs within a computer, such activity is not determinative of whether the process is statutory because such transformation alone does not distinguish a statutory computer process from a nonstatutory computer process. What is determinative is not how the computer performs the process, but what the computer does to achieve a practical application. See *Arrhythmia*, 958 F.2d at 1057, 22 USPQ2d at 1036.

A process that merely manipulates an abstract idea or performs a purely mathematical algorithm is nonstatutory despite the fact that it might inherently have some usefulness. In *Sarkar*, 588 F.2d at 1335, 200 USPQ at 139, the court explained why this approach must be followed:

No mathematical equation can be used, as a practical matter, without establishing and substituting values for the variables expressed therein. Substitution of values dictated by the formula has thus been viewed as a form of mathematical step. If the steps of gathering and substituting values were alone sufficient, every mathematical equation, formula, or algorithm having any practical use would be per se subject to patenting as a "process" under 101. Consideration of whether the substitution of specific values is enough to convert the disembodied ideas present in the formula into an embodiment of those ideas, or into an application of the formula, is foreclosed by the current state of the law.

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For such subject matter to be statutory, the claimed process must be limited to a practical application of the abstract idea or mathematical algorithm in the technological arts. See *Alappat*, 33 F.3d at 1543, 31 USPQ2d at 1556-57 (quoting *Diamond v. Diehr*, 450 U.S. at 192, 209 USPQ at 10). See also *Alappat* 33 F.3d at 1569, 31 USPQ2d at 1578-79 (Newman, J., concurring) ("unpatentability of the principle does not defeat patentability of its practical applications") (citing *O'Reilly v. Morse*, 56 U.S. (15 How.) at 114-19). A claim is limited to a practical application when the method, as claimed, produces a concrete, tangible and useful result; i.e., the method recites a step or act of producing something that is concrete, tangible and useful. See *AT&T*, 172 F.3d at 1358, 50 USPQ2d at 1452. Likewise, a machine claim is statutory when the machine, as claimed, produces a concrete, tangible and useful result (as in *State Street*, 149 F.3d at 1373, 47 USPQ2d at 1601) and/or when a specific machine is being claimed (as in *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557 (in banc)). For example, a computer process that simply calculates a mathematical algorithm that models noise is nonstatutory. However, a claimed process for digitally filtering noise employing the mathematical algorithm is statutory."

By analyzing the above examples given in MPEP, it is easy to see that the methods claimed by Applicants do not result in concrete and tangible products resulting in a physical transformation outside of the computer. Comparing a sequence (a non-functional descriptive material) to another sequence (a non-functional descriptive material) results in a string of data, which also constitute non-functional descriptive material, since no physical transformation of the data has occurred outside of the computer.

Therefore the art rejection is maintained, with the addition of new claims 59-72, as necessitated by Applicants' amendment.

Claim Rejections - 35 USC § 101 Utility

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. The pending claims have been reviewed in light of the the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

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The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

7. Claims 58-72 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Claims 58-72 are drawn to methods of identifying a nucleotide sequence comprising comparing target sequence to a sequence stored in a computer readable medium having recorded thereon at least 100 nucleotide sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof.

Patentability of these claims is based on a computer readable medium with at least 100 nucleic acid sequences recoded thereon. These sequences were obtained from a genome of *EmERICELLA NIDULANS*. However, there is no indication in the specification of what are the functions of any of the sequences with SEQ ID NO: 16207-27905. The claimed subject matter is not supported by a specific or substantial utility because the disclosed uses are generally applicable to any sequence data recorded on computer readable medium. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use. For example, if these at least 100 sequences were used in the method of claim 58 for comparison

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with sequences of known function, this would constitute further characterization of these at least 100 sequences. Comparison of these at least 100 sequences with other unknown sequences would also lead to further investigation of their properties.

Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

8. Claims 58-72 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Remarks concerning the art rejection

9. The following is used as a basis for the rejection of claims 58-72.

MPEP 2106. IV.B.1(b)

(b) Nonfunctional Descriptive Material

Descriptive material that cannot exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition of matter and should be rejected under 35 U.S.C.101. Thus, Office personnel should consider the claimed invention as a whole to determine whether the necessary functional interrelationship is provided. Where certain types of descriptive material, such as music, literature, art, photographs and mere arrangements or compilations of facts or data, are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer. Such "descriptive material" is not a process, machine, manufacture or composition of matter. (Data consists of facts, which become information when they are seen in context and convey meaning to people. Computers process data without any understanding of what that data represents. Computer Dictionary 210 (Microsoft Press, 2d ed. 1994).) The policy that precludes the patenting of nonfunctional descriptive material would be easily frustrated if the same descriptive material could be patented when claimed as an article of manufacture. For example, music is commonly sold to consumers in the format of a compact disc. In such cases, the known compact disc acts as nothing more than a carrier for nonfunctional descriptive material. The purely nonfunctional descriptive material cannot alone provide the practical application for the manufacture.

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MPEP 2106.VI Patentable Subject Matter — Computer-Related Inventions

If the difference between the prior art and the claimed invention is limited to descriptive material stored on or employed by a machine, Office personnel must determine whether the descriptive material is functional descriptive material or nonfunctional descriptive material, as described supra in paragraphs IV.B.1(a) and IV. B.1(b). Functional descriptive material is a limitation in the claim and must be considered and addressed in assessing patentability under 35 U.S.C. 103. Thus, a rejection of the claim as a whole under 35 U.S.C. 103 is inappropriate unless the functional descriptive material would have been suggested by the prior art. In re Dembiczak, 175 F.3d 994, 1000, 50 USPQ2d 1614, 1618 (Fed. Cir. 1999). Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. Cf. In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability).

Common situations involving nonfunctional descriptive material are:

- a computer-readable storage medium that differs from the prior art solely with respect to nonfunctional descriptive material, such as music or a literary work, encoded on the medium,
- a computer that differs from the prior art solely with respect to nonfunctional descriptive material that cannot alter how the machine functions (i.e., the descriptive material does not reconfigure the computer), or
- a process that differs from the prior art only with respect to nonfunctional descriptive material that cannot alter how the process steps are to be performed to achieve the utility of the invention.

10. Sequences stored on a computer readable medium are therefore considered as non-functional descriptive material.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 58-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez-Tome et al. (Nucl. Acids Res., vol. 24, pp. 6-12, 1996; cited in the previous office action).

Regarding claims 58-72, Rodriguez-Tome et al. teach CD-ROM with containing EMBL nucleotide sequence database (page 6, second paragraph). Rodriguez-Tome et al. teach that the CD-

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ROM also contains software for data query and retrieval (page 9, the last paragraph; page 10, first paragraph). Rodriguez-Tome et al. teach comparing users' sequences (= target sequences) to sequence in the EMBL nucleotide sequence database (page 10, paragraph 8).

It would have been *prima facie* to obvious for one of ordinary skill in the art to have used a computer system comprising a CD-ROM of Rodriguez-Tome et al. to perform sequence searches against a collection of sequence data. The motivation to do so would have been that using CD-ROM made database searches accessible to clients without Internet access.

13. No claims are allowed.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TS
March 16, 2004


MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
3.22.04

Notice to Comply

Application No.

09/404,520

Examiner

Teresa E Strzelecka

Applicant(s)

CAO ET AL.

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NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other:

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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